

5. 510(k) Summary

Submitter's Name: Fotona d.d.
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MAR 28 2012

Date: December 14, 2011

Device Trade Name: Fotona XP Nd:YAG Laser System Family
 Common Name: Nd:YAG Surgical Laser
 Classification Name: Instruments, Surgical, Powered, Laser
 79-GEX

DEVICE DESCRIPTION

The Fotona XP Nd:YAG Laser System Family is based on the Nd:YAG (1064 nm) laser technology. There is one optical cavity containing the Nd:YAG crystal. The Nd:YAG laser is activated by means of the use of a flashlamp. After the cavity, a red diode aiming beam is reflected onto a coaxial beam path using a beamsplitter assembly. The combined therapeutic and aiming beams are guided by an optical fiber delivery system to an optical handpiece. Optionally, the laser beams can be guided through fiber having SMA905 connector on the proximal end and bare fiber on distal end. The user activates laser emission by means of a footswitch.

The Nd:YAG (1064 nm) laser can be operated with variable pulse durations in the range of 0.1-50 msec, with repetition rates up to 100 Hz and laser pulse energies up to 20 J. Depending on the type of treatment, the user can choose between a PULSE mode user interface, and a QCW (Quasi-Continuous Wave) mode user interface. The laser operation is the same for both modes, the difference is only in the laser parameters that can be directly selected from the keyboard.

INTENDED USE

Fotona XP Nd:YAG Laser System Family and its accessories are intended for use in the following procedures:

Podiatry (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:

- Matrixectomy
- Radical nail excision
- Periungual and subungual warts
- Plantar warts
- Neuromas
- Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum* and *T. mentagrophytes*, and/or yeasts *Candida albicans*, etc.)

PREDICATE DEVICES

- Cutera GenesisPlus (K103626)
- PinPointe FootLaser (K093547)

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The Fotona XP Laser System Family has identical technological and similar design characteristics as the predicate devices. The output characteristics are for the intended use the same as those of the predicate devices.

A comparison of the technical characteristics for the intended use of the Fotona XP Laser System Family with those of the predicate devices is provided in the Table 1 below.

Table 1: Comparison table between Fotona XP Nd:YAG Laser System Family and predicate devices

Characteristic	Fotona XP Nd:YAG Laser System Family	PinPointe Footlaser K093547	Cutera GenesisPlus Laser K103626
Laser source	Nd:YAG	Nd:YAG	Nd:YAG
Wavelength	1064 nm	1064 nm	1064 nm
Laser media	Flashlamp pumped solid state rod	Flashlamp pumped solid state rod	Flashlamp pumped solid state rod
Aiming beam	650 nm (≤ 1 mW)	630-680 nm ($\leq 2,5$ mW)	630-680 nm ($\leq 2,5$ mW)
Output mode	Pulsed, Multimode	Pulsed, Multimode	Pulsed, Multimode
Energy per pulse	up to 3,5 J (podiatry) up to 20 J (other indications)	up to 3,5 J	up to 3,5 J
Pulsewidth	0,1 – 2 ms (podiatry) 0,1 – 50 ms (other indications)	0,1 – 3 ms	0,1 – 3 ms 6 – 20 ms (other indications)
Repetition rate	1 – 100 Hz	5 – 100 Hz	5 – 100 Hz
Output power	up to 30 W	up to 100 W	up to 100 W
Beam delivery	Fiber	Fiber	Fiber
Spot sizes	1 -1.5 mm (podiatry) 0,2 – 10 mm (other indications)	1 -1.5 mm (podiatry) Other spot sizes are not published	1-1.5 mm (podiatry) up to 13 mm (other indications)
User interface	Push-button control panel	LCD color touchscreen or push-button control panel	LCD color touchscreen
Laser activation	Footswitch	Footswitch	Footswitch
Input power	230V, 17A 50/60 Hz	200-240V, 50/60 Hz	NA
Dimensions	60x33x82 cm	33x36x81 cm	NA
Weight	78,5 kg (maximum power configuration)	17,2 kg	NA

STATEMENT OF SUBSTANTIAL EQUIVALENCE

Fotona XP Nd:YAG Laser System Family is substantially equivalent to the predicate devices Cutera GenesisPlus (K103626) and PinPointe FootLaser (K093547) in terms of indications for use and technology based on technical and functional characteristics.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 13, 2013

Fotona D.D.
% Mr. Stojan Trošt
QA/RA Manager
Stegne 7
SI-1000 Ljubljana, Slovenia

Re: K113702

Trade/Device Name: Fotona XP Nd:YAG Laser System Family
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and
plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: PDZ, GEX
Dated: February 27, 2012
Received: February 29, 2012

Dear Mr. Trošt:

This letter corrects our substantially equivalent letter of March 28, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,
FOR
Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1113702

4. Indications for Use Statement

510(k) Number (if known):

Device Name: Fotona XP Nd:YAG Laser System Family

Fotona XP Nd:YAG Laser System Family is indicated for podiatry (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:

- Matrixectomy
- Radical nail excision
- Periungual and subungual warts
- Plantar warts
- Neuromas
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Prescription Use: X
(21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use: _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. [Signature] for *mxm*
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K 113702